

REMARKS

Applicants respectfully request entry of the foregoing and reconsideration of the subject matter identified in caption, as amended, pursuant to and consistent with 37 C.F.R. §1.112, and in light of the remarks which follow.

Claims 1-2, 5-7, 9-10, 13-15, 17-18, 21, 38-39, 41-42, 44-53, 55-59, 61-65 and 67-69 are pending in the application, Claims 11, 19, 43, 54, 60 and 66 having been canceled above.

By the above amendments, Applicants deleted "inorganic salts of manganese, manganese-rich plant extracts" from Claims 1, 2, 5, 47, 48 AND 49. Applicants also deleted "alverine," "alverine salts," and "chlorine-channel openers," from Claims 48 and 49. Applicants further amended Claim 49 by adding --keratolytic agents, hydroxy acids and retinoids-- after the words "at least one member selected from the group consisting of." Applicants also deleted "at least one inorganic or" from Claims 9, 17, 41, 52, 58 and 64. In addition, Applicants canceled Claims 11, 19, 43, 54, 60 and 66 without prejudice to or disclaimer of the subject matter therein. Finally, Applicants re-wrote Claims 6, 14, 38, 50, 56 and 62 in independent form to further emphasize the patentability of the combinations of features recited in these claims.

Applicants thank the Examiner for acknowledging Applicants' claim for foreign priority under 35 U.S.C. §119 and for indicating that all certified copies of the priority documents have been received. Applicants also thank the Examiner for the initialed Forms PTO-1449 dated September 22, 2003, February 17, 2004, and January 3, 2006.

Turning now to the Official Action, Applicants understand that the requirement for restriction/election has been made final and that Claims 5, 38-39, 41-44, 49 and

62-67 stand withdrawn as being directed to non-elected subject matter. Applicants reserve the right to file a divisional application directed to the subject matter of these withdrawn claims.

The Official Action asserts that the Information Disclosure Statement (IDS) filed September 22, 2003, does not comply with 37 C.F.R. §1.98(a)(2) because it does not provide a legible copy of JP 403017004A. In an effort to ensure entry and formal consideration of JP '004, Applicants submit the attached IDS again citing JP '004 and providing a legible copy thereof. Applicants respectfully request that the next official communication acknowledge entry and formal consideration of JP '004.

Claims 48, 56-61 and 69 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. For at least the reasons that follow, withdrawal of the rejection is in order.

In order to obviate the rejection of Claim 48, Applicants amended Claim 48 by deleting "alverine", "alverine salts," and "chlorine-channel openers."

Applicants respectfully request reconsideration and withdrawal of the §112, second paragraph, rejection of Claims 48, 56-61 and 69.

Claims 1-2, 9, 13, 17, 21, 47, 52 and 55 stand rejected under 35 U.S.C. §102(b) as being anticipated by JP 04108710 to Shiga. For at least the reasons that follow, withdrawal of the rejection is in order.

Independent Claim 1, as amended above, recites a method for combating skin pallor resulting from stress, comprising topically administering to an individual subject afflicted with skin pallor resulting from stress, a cosmetic/dermatological composition consisting of: an effective skin pallor-reducing amount of at least one form of manganese selected from the group consisting of organic salts of

manganese, and manganese-rich microorganism extracts; water; and at least one member selected from the group consisting of topically applicable, physiologically acceptable alcohols, oils, fatty acids, waxes, emulsifiers, hydrophilic gelling agents, lipophilic gelling agents, preservatives, antioxidants, fragrances, fillers, UV-screening agents, dyestuffs, colorants, keratolytic agents, alverine, alverine salts, chlorine-channel openers, hydroxy acids and retinoids. (Emphasis added).

Claim 2, as amended above, recites a method for combating skin pallor resulting from stress, comprising topically administering to an individual subject afflicted with skin pallor resulting from stress, a cosmetic/dermatological composition consisting of: an effective skin pallor-reducing amount of at least one form of manganese selected from the group consisting of organic salts of manganese, and manganese-rich microorganism extracts; a bioaffecting amount of at least one member selected from the group consisting of alverine, alverine salts, keratolytic agents, chlorine-channel openers, hydroxy acids and retinoids; water; and at least one member selected from the group consisting of topically applicable, physiologically acceptable alcohols, oils, fatty acids, waxes, emulsifiers, hydrophilic gelling agents, lipophilic gelling agents, preservatives, antioxidants, fragrances, fillers, UV-screening agents, dyestuffs and colorants. (Emphasis added.)

Claim 47, as amended above, recites a method for combating skin pallor resulting from stress, comprising topically administering to an individual subject afflicted with skin pallor resulting from stress, a cosmetic/dermatological composition comprising: an effective skin pallor-reducing amount of at least one form of manganese selected from the group consisting of organic salts of manganese, and manganese-rich microorganism extracts, said at least one form of manganese being

the sole active ingredient for treating skin pallor resulting from stress in the composition; and a topically applicable, physiologically acceptable vehicle, diluent or carrier therefor. (Emphasis added.)

Shiga relates to fine particles of demagnetized ferromagnetic material such as magnetite (i.e., Fe_3O_4) or manganese zinc ferrite (i.e., $\text{Mn-Zn-Fe}_2\text{O}_3$) dispersed in a medium solidifying after use (preferably a dispersion medium selected from a film-forming polymeric viscous substance and a gel-forming montmorillonite or an oil and fat, etc.) and the dispersion is used as a magnetic cosmetic capable of forming a cosmetic film of a magnetized magnetic material having blood flow promoting effect by magnetizing the fine particles after dispersed or compounded in the medium in fixed state. The agglutination of the particles by the magnetism during the preparation of the cosmetic can be prevented by this process. (See Shiga at Abstract).

The Official Action asserts that "it is the Examiner's position that a composition that is utilized for increasing microcirculation will implicitly treat skin pallor since skin pallor is caused by the lack of blood flow; thus increasing blood flow will decrease skin pallor." (See Official Action at page 4.)

It is well-established that in order to demonstrate anticipation under §102(b), each feature of the claim at issue must be found, either expressly described or under principles of inherency, in a single prior art reference. See *Kalman v. Kimberly-Clark Corp.*, 218 U.S.P.Q. 798 (Fed. Cir. 1983). That is not the case here.

In particular, independent Claims 1, 2 and 47 are directed topical administration of a composition including an effective skin pallor-reducing amount of at least one form of manganese selected from the group consisting of organic salts

of manganese and manganese-rich microorganism extracts. (Emphasis added.)

Nowhere does Shiga disclose or fairly suggest methods for combating skin pallor comprising topically administering such a composition, as recited in independent Claims 1, 2 and 47.

Accordingly, Applicants submit that Claims 1, 2 and 47 are patentable over Shiga. The remaining claims (Claims 9, 13, 17, 21, 52 and 55) depend, directly or indirectly, from independent Claims 1, 2 or 47 and are therefore also patentable over Shiga for at least the reasons that Claims 1, 2 and 47 are patentable.

Reconsideration and withdrawal of the §102(b) rejection over Shiga are respectfully requested.

Claims 1-2, 6-7, 13-15, 21, 47, 50-51 and 55 stand rejected under 35 U.S.C. §102(e) as being anticipated by Pauly (U.S. Patent No. 6,274,103). For at least the reasons that follow, withdrawal of the rejection is in order.

Pauly relates to the field of cosmetology and dermatology, and has for its object the use for cosmetic, dermatologic or pharmaceutical applications, of a plant extract of the genus *Adansonia*, more particularly of the species *Adansonia digitata* (*baobab*), as well as a cosmetic and/or pharmaceutical product or composition for the skin and/or the hair, eyelashes or nails, comprising such an extract. (See Pauly at column 1, lines 5-13.)

Again, to demonstrate anticipation under §102, each feature of the claim at issue must be found, either expressly described or under principles of inherency, in a single prior art reference. See *Kalman v. Kimberly-Clark Corp.*, 218 U.S.P.Q. 798 (Fed. Cir. 1983). That is not the case here.

Independent Claims 1, 2 and 47 are directed to methods for combating skin pallor comprising topically administering a composition including an effective skin pallor-reducing amount of at least one form of manganese selected from the group consisting of organic salts of manganese and manganese-rich microorganism extracts. (Emphasis added.) Nowhere does Pauly disclose or fairly suggest methods for combating skin pallor by topically administering a composition including an effective skin pallor-reducing amount of at least one form of manganese selected from the group consisting of organic salts of manganese and manganese-rich microorganism extracts. In fact, Pauly fails to disclose or fairly suggest topically administering any specific amount of manganese, let alone an effective skin pallor-reducing amount of manganese in the form of an organic salt of manganese or manganese-rich microorganism extract, as claimed. Accordingly, Pauly fails to expressly or inherently describe each feature of independent Claims 1, 2 and 47.

For at least these reasons, Claims 1, 2 and 47 are patentable over Pauly. The remaining claims (Claims 6-7, 13-15, 21, 50-51 and 55) depend, directly or indirectly, from independent Claims 1, 2 or 47, or otherwise include all of the features of Claims 1, 2 or 47, and are therefore also patentable over Pauly for at least the reasons that Claims 1, 2 and 47 are patentable.

Claims 1-2, 6-7, 9-11, 13-15, 17-19, 21, 45-48, 60-61 and 68-69 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Breton (U.S. Patent No. 5,900,257) alone or in combination with "Questions and Answers About Raynaud's Phenomenon," distributed by the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMSD article). For at least the reasons that follow, withdrawal of the rejection is in order.

Independent Claims 1, 2 and 47 are presented above.

Independent Claim 48, as amended above, is directed to a method for combating skin pallor resulting from stress, comprising topically administering to an individual subject afflicted with skin pallor resulting from stress, a cosmetic/dermatological composition comprising: (i) an effective skin pallor-reducing amount of at least one form of manganese selected from the group consisting of organic salts of manganese, and manganese-rich microorganism extracts; (ii) a bioaffecting amount of at least one member selected from the group consisting of keratolytic agents, hydroxy acids and retinoids, said at least one form of manganese being the sole active ingredient for treating skin pallor resulting from stress in the composition; and a topically applicable, physiologically acceptable vehicle, diluent or carrier therefor. (Emphasis added.)

Breton '257 relates to novel cosmetic/dermatological or pharmaceutical compositions comprising at least one lanthanide, manganese, tin or yttrium salt as a substance P antagonist, for the treatment of disorders associated with an excessive synthesis and/or release of substance P and, more specifically, for the treatment of sensitive skins. (See Breton '257 at column 1, lines 5-15).

To establish a *prima facie* case of obviousness, the prior art references (or references when combined) must teach or suggest all of the claimed features. See *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). In addition, "all words in a claim must be considered in judging the patentability of that claim against the prior art." See *In re Wilson*, 424 F.2d 1382, 1385; 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970). See M.P.E.P. §2143.03.

As indicated above, independent Claims 1, 2, 47 and 48 are directed to methods for combating skin pallor by administering a composition including an effective skin pallor-reducing amount of at least one form of manganese selected from the group consisting of organic salts of manganese and manganese-rich microorganism extracts. Nowhere does Breton disclose or fairly suggest administering a composition including an effective skin pallor-reducing amount of at least one such form of manganese. Furthermore, the methods of independent Claims 1, 2, 47 and 48 are directed to topical administration of such composition. Again, Applicants submit that Breton '257 does not disclose or fairly suggest a combating skin pallor by topically administering the particular compositions claimed in Claims 1, 2, 47 and 48.

The NIAMSD article does not overcome the above deficiencies of Breton '257. That is, the NIAMSD article (alone or in combination with Breton) does not disclose or fairly suggest the methods recited in Claims 1, 2, 47 and 48. In particular, there is no disclosure or suggestion that one should or even could combat skin pallor by topically administering to an individual afflicted with skin pallor resulting from stress a composition including an effective skin pallor-reducing amount of at least one form of manganese selected from the group consisting of organic salts of manganese and manganese-rich microorganism extracts. Thus, Applicants respectfully submit that the asserted combination of Breton '257 in view of the NIAMSD article does not teach or suggest all of the claimed features and does not reflect a proper consideration of "all words" in Claims 1, 2, 47 and 48.

Accordingly, Claims 1, 2, 47 and 48 are patentable over the combination of Breton '257 in view of the NIAMSD article. The remaining claims (Claims 6-7, 9-11,

13-15, 17-19, 21, 45-46, 50-61 and 68-69) depend, directly or indirectly, from independent Claims 1, 2, 47 and 48, or otherwise include all of the features of these claims, and are therefore also patentable over the asserted combination for at least the reasons that Claims 1, 2, 47 and 48 are patentable. Applicants respectfully request reconsideration and withdrawal of the rejection.

Finally, Applicants have rewritten Claims 6, 14, 50, and 56 in independent form. Applicants submit that these claims are also patentably distinguished from the cited prior art references because none of the cited references, alone or in combination, discloses or fairly suggests a method for combating skin pallor resulting from stress comprising topically administering to an individual subject afflicted with skin pallor resulting from stress, a composition including an effective skin pallor-reducing amount of at least one form of manganese selected from the group consisting of organic salts of manganese and manganese-rich microorganism extracts, wherein from 0.0001% to 1% by weight of manganese is administered. Furthermore, Applicants submit that dependent Claims 9, 10, 17, 18, 41, 42, 45, 46, 52, 53, 58, 59, 68, and 69 are also separately patentable over the cited prior art, because none of the prior art references, alone or in combination, discloses or fairly suggests methods that employ compositions that include manganese in the form of an organic salt, let alone the specific organic salts recited in these dependent claims.

From the foregoing, Applicants earnestly solicit further and favorable action in the form of a Notice of Allowance.

If there are any questions concerning this paper or the application in general, Applicants invite the Examiner to telephone the undersigned at the Examiner's earliest convenience.

Respectfully submitted,

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